A randomized clinical trial of the effectiveness of 0.018-inch and 0.022-inch slot orthodontic bracket systems

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A randomised clinical trial of the effectiveness of 0.018-inch and 0.022-inch slot orthodontic bracket systems: Part 2. Quality of treatment

SUMMARY

Objective: To compare the quality of orthodontic treatment between 0.018-inch and 0.022-inch slot bracket systems.

Subjects and Methods: Eligible participants aged 12 years or over were allocated to the 0.018-inch or 0.022-inch slot MBT appliance (3M-Unitek, Monrovia, California) using block randomisation in groups of ten. Outcome measures included: (1) ABO CR-EVAL (2) PAR scores (3) incisor inclination and (4) patient perception using the Index of Orthodontic Treatment Need aesthetic component (IOTN AC) and three validated questionnaires before, during and after treatment. Parametric tests (independent samples t-test and two-way ANOVA) and non-parametric tests (Chi-square with Fisher's exact tests and Mann-Whitney U-test) assessed differences between groups ($P < 0.05$).

Results: Of the 187 participants randomised (1:1 ratio), 34 withdrew or were excluded (protocol deviations or poor cooperation). There were 77 patients in the 0.018-inch slot group and 76 patients in the 0.022-inch slot group (overall mean age: 19.1 years). Baseline characteristics were similar between groups ($P > 0.05$). The mean total ABO CR-EVAL scores were 34.7 and 34.5; mean percentage PAR score reduction 74.1% and 77.1%; mean change for maxillary incisor inclination 2.9° and 1.6° and for mandibular incisor inclination 2.7° and 1.4° for the 0.018-inch and 0.022-inch groups, respectively. Improvement in patient perception of aesthetics after treatment was statistically significant for both groups ($P < 0.05$). However, there were no statistically significant differences between the two treatment groups for ABO CR-EVAL, percentage PAR score reduction, incisor inclination, and patient perception of treatment ($P > 0.05$). No adverse events were observed during treatment.

Limitations: It was impossible to blind clinicians or patients to allocation and oral hygiene and periodontal outcomes were not assessed.

Conclusions: There were no statistically or clinically significant differences in the quality of occlusal outcomes, incisor inclination and patient perception of treatment between 0.018-inch and 0.022-inch slot bracket systems.

Conflict of interest: The authors declare no conflict of interest.

Registration: The trial was registered with ClinicalTrials.gov on 5th March 2014, registration number: NCT02080338.

INTRODUCTION

The 0.018-inch and 0.022-inch slot size bracket systems were developed following metallurgical advances in archwire materials with each system having specific features, and differing benefits and drawbacks. Both systems continue to be widely used by clinicians worldwide with claims over clinical advantages and superiority of each system. However, to date, there is no robust scientific evidence to support orthodontic treatment with either slot size in preference to the other, as all the available comparisons between the two slot sizes are of low quality. This leaves the choice of bracket slot size as subjective. There has been a long debate about the reason for the existence of two bracket slot size systems, with calls for one rather than two standards. (1-4)

There may be biomechanical advantages and disadvantages associated with both 0.018-inch and 0.022-inch slot brackets. It has been postulated that 0.018-inch brackets have fewer choices in archwire dimensions and greater capacity for total slot 'fill' overall and earlier in treatment allowing better torque control of anterior teeth. On the other hand, 0.022-inch brackets have more archwire options and allow better archwire sliding with less friction. However using a full size archwire with 0.022-inch brackets is restricted due to reduced springiness and high forces associated with the larger archwire dimensions.[3] National surveys within the United States and United Kingdom have revealed that the majority of

orthodontists prefer the 0.022-inch slot brackets and this is mainly attributed to the perception of better treatment outcomes, but not based on scientific evidence. (5-9)

Amditis and Smith (2000) (10) used the PAR scoring index to evaluate treatment outcome between the two bracket slot size systems, but they did not provide any comparison between the groups. Detterline et al. (2010) (11) found that the ABO CR-EVAL results favoured the 0.018-inch slot bracket group. However, the difference was statistically but not clinically significant.

A potential for higher torque to be delivered by the 0.018-inch slot brackets has been shown in different experimental studies. (12-14) Nevertheless, these studies were laboratory-based and the influence of other factors in practice, such as intra-oral ageing of fixed appliances and the influence of saliva, among others, were not considered.

There are no clinical trials that have compared the two bracket slot sizes in terms of quality of treatment.

Specific objectives or hypotheses

This study is the second report of a randomised clinical trial that prospectively compared the effectiveness of orthodontic treatment with the two bracket slot sizes. Here we present the secondary outcomes of the trial in terms of quality of treatment. The null hypothesis was 'There is no significant difference in orthodontic treatment with the 0.018-inch or 0.022-inch slot bracket systems in terms of [1] occlusal outcomes when measured using the ABO CR-EVAL, PAR index, and incisor inclination (near end of orthodontic treatment), and [2] patient perception with fixed appliances orthodontic treatment (experience and satisfaction)'. Parts 1 and 3 (15,16) report the results for the duration of treatment and biological side effects of treatment, respectively.

SUBJECTS AND METHODS

Trial design and any changes after trial commencement

This was a 2-arm parallel active group randomised clinical trial with a 1:1 allocation ratio. There were no changes to the method after trial commencement.

Participants, eligibility criteria, and setting

In the UK, state-funded orthodontic treatment is provided through the NHS for patients scoring Index of Orthodontic Treatment Need (IOTN) Dental Health Component (DHC) 3 Aesthetic Component (AC) 6 and above (moderate to complex cases) by office-based Specialist Orthodontists working with a team of Orthodontic Therapists, and hospital/faculty Orthodontists trained to Consultant level who also provide competitive-entry graduate programs for Specialist and Consultant-level training. All patients referred for hospital Orthodontic care from January 2010 to September 2014 with good oral hygiene and a caries-free dentition were invited to participate in the study. The study was conducted in three sites however, one site was unable to recruit to the study and so was withdrawn, leaving two sites that contributed the participants for the study. The participants were selected according to the following criteria: aged 12 years and above with any type of malocclusion who were scheduled for dual arch fixed appliance orthodontic treatment. The exclusion criteria for the study were patients who had [1] undergone previous orthodontic treatment/functional appliances, [2] orofacial clefts, [3] severe hypodontia, [4] special needs, and [5] required orthodontic-orthognathic surgery treatment. They did not take part and were not included in any analysis. Patients who met the inclusion criteria for the study received the patient information sheet and where relevant, the parent information sheet was also issued. The consent process was completed after obtaining patient/parent assent to participate in the study.

The work was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki). Ethical approval was obtained from the NHS Tayside Committee on Medical Research Ethics (East of Scotland Ethics Service) in October 2009 (REC Reference: 09/S1401/56) and Research and Development (R&D) approval was obtained from the NHS Tayside Research and Development in November 2009.

Interventions

The treatment involved initially polishing the teeth with pumice and water, and using a self-etching primer (Transbond™ Plus Self Etching Primer, 3M-Unitek, Monrovia, USA) to prepare the teeth for bracket placement. Adhesive pre-coated (APC) brackets/buccal tubes (APC™ II Victory Series™ Twin MBT™, 3M-Unitek, Monrovia, USA) were bonded according to the allocation group, i.e. either 0.018-inch or 0.022-inch slot MBT prescription. Bands were used on molars where a transpalatal arch or quadhelix was required.

A predetermined archwire sequence for each bracket slot system was followed (**{** HYPERLINK "http://multimedia.3m.com/mws/media/736576O/wire-selection-for-optimal-biomechanic-efficiency-dr-d-segner.pdf" **}**). The archwire sequence for the 0.018-inch bracket slot system was: 0.016-inch super elastic nickel-titanium, 0.016 × 0.022-inch super elastic nickel-titanium, and 0.016 × 0.022-inch stainless steel archwires. For the 0.022-inch bracket slot system, the sequence was: 0.016-inch super elastic nickel-titanium, 0.019 × 0.025-inch super elastic nickel-titanium, and 0.019 × 0.025-inch stainless steel archwires. Appliances were routinely adjusted at an interval of 6-8 weeks. All appliances were ligated using conventional elastomeric ligation unless stainless steel ligatures were required for severely rotated or ectopic teeth. All the participants received a standard treatment regime according to the treatment protocol throughout the trial. Extraction spaces were closed using sliding mechanics with closed coil springs or elastomeric chains. Minor deviations from the standard protocol were accepted for certain clinical circumstances (e.g. use of "piggy back" wires), but no special techniques or additional appointments were required for the study. Appliances were debonded and retainers provided when a Class I incisor and canine relationship, a well intergiditating buccal segment relationship and all other treatment goals had been established. Prematurely terminated cases were due to poor patient compliance.

Periapical radiographs with a long cone paralleling technique for the maxillary central incisors were taken at the start of treatment and after nine months from the start of treatment. In addition, digital lateral cephalometric radiographs were taken at the start and near end of treatment (by the end of the finishing stage of treatment) [UK orthodontic radiography guidelines by Isaacson et al. (2008) (17), updated by Isaacson et al. (2015) (18)].

Outcomes and any changes after trial commencement

This study presents the secondary outcome measures of the RCT which were quality of occlusal outcomes; ABO CR-EVAL, PAR index, incisor inclination (near end of orthodontic treatment), and patient perception; experience and satisfaction with fixed appliances orthodontic treatment. All the records were anonymised and the measurements (except PAR index) were undertaken by the principal investigator who was masked to the study group allocation during assessment and therefore identification of the group allocation was not possible. All the trial documents were labeled with study ID number, which together with the unique hospital identification number and model box number were used for participant identification and data collection. It should be noted that none of these numbers revealed the allocation group. There were no outcome changes after trial commencement except for the dropout of one of the centres, however, since this was at the beginning of recruitment, it did not impact on the study results. The other two centres were able to recruit a sufficient number of patients.

ABO Cast-Radiograph Evaluation (CR-EVAL)

The guidelines for study model analysis were obtained from the instructions provided by the American Board of Orthodontics. (19) This study only included the model analysis and excluded the panoramic radiographic analysis (root angulation component) because the trial did not involve post-treatment panoramic radiographs in accordance with the UK orthodontic radiography guidelines. (17,18) Study models with bubbles or broken teeth or those that were incorrectly trimmed were excluded.

The components of the ABO CR-EVAL measured in this study were: alignment, marginal ridges, buccolingual inclination, overjet, occlusal contacts, occlusal relationship, and interproximal contacts. Post-treatment study models were measured according to the above seven criteria and scored as 0, 1, or 2 depending on the amount of deviation from the standards established by the ABO. (19) The overall score

of the ABO CR-EVAL for each treated case represented the sum of points for these criteria. The investigator (Y.A.Y.) was calibrated with the aid of the ABO calibration kit and the demonstration video by the former head of the ABO { HYPERLINK "https://www.americanboardortho.com/orthodontic-professionals/about-board%20certification/downloads-and-references/measurement-demonstration/" }.

Peer Assessment Rating (PAR index)

The Peer Assessment Rating (PAR, with British weightings) was used to measure the severity of malocclusion on study models before treatment and to identify the degree of improvement after treatment. (20) The scoring was performed by an Orthodontic Technician who was calibrated with PAR measurement and was also masked to study group allocation.

Incisor inclination

The inclination of the maxillary incisor to the palatal plane (U1-PP) and mandibular incisor to the mandibular plane (L1-MP) were measured before treatment and near end of treatment by calculating the angle between the long axis of the maxillary central incisors and the maxillary/palatal plane (anterior nasal spine – posterior nasal spine) (21) and the angle between the long axis of mandibular central incisors and the mandibular plane (Gonion – Menton) (22,23). Every lateral cephalometric radiograph was digitised using the AutoCAD® 2007 (www.autodesk.co.uk) software program to calculate the angular measurements. The angles were measured directly as they were not affected by magnification.

Patient perception

The participants completed three questionnaires throughout the trial. The Pre-treatment Questionnaire assesses patient expectations with fixed appliance orthodontic treatment and was completed before commencing treatment. The Orthodontic Experience Questionnaire evaluates experience with fixed appliance orthodontic treatment and was completed six months from the start of treatment during one of the routine appliance adjustment appointments. The Post-treatment Questionnaire measures the impact of fixed appliance orthodontic treatment and patient satisfaction with treatment and was completed at the end of treatment. All these questionnaires have been validated for use by patients undergoing fixed appliances orthodontic treatment. (24)

The Index of Orthodontic Treatment Need – Aesthetic Component (IOTN AC) was also used for self-rating of dental attractiveness before and after treatment. (25) This was assessed by the participant using the standard IOTN AC images.

Sample size calculation

Although patients were recruited in this clinical trial according to the sample size calculation for the primary outcome, an a priori power analysis was also carried out for the ABO CR-EVAL as a representative of the secondary outcomes. The sample size was calculated to detect a difference of 5 points in the mean total ABO CR-EVAL score which was considered as a clinically significant difference (11,26) with the standard deviation was taken from Detterline et al. (2010) (11). A sample size of 73 patients in each group was expected to have 80% power to detect this difference where the effect size was calculated as a Cohen's D of 0.47 at P = 0.05.

Interim analyses and stopping guidelines

This was determined if severe apical root resorption was detected nine months from the start of treatment using periapical radiographs in the majority of patients in one group. This would mandate that the trial monitoring committee should be convened to consider whether the study would be terminated. This evaluation was undertaken by an independent clinician in order to preserve masking regarding the study groups.

Randomisation

Block randomisation was used to form the allocation list for the two comparison groups. A computer random number generator was implemented to select random permuted blocks with a block size of ten and an equal allocation ratio ({ HYPERLINK "http://www.graphpad.com/quickcalcs/randomn2.cfm" }). Then, the final Allocation Table for the participants in the study (which contained the study number and allocation group) was kept in a sealed envelope away from the clinical environment.

Allocation concealment was achieved with sequentially numbered, identical, opaque, and sealed envelopes which were prepared before the trial and contained the treatment allocation card. These were kept in a box and as the clinician obtained the informed consent, an independent dental nurse was responsible for identifying the next allocation envelope in the sequence to implement the randomisation process.

Blinding

Due to the nature of this orthodontic trial, blinding to treatment allocation was only possible for the investigator and data analyst, while it was not possible for the clinicians and patients. The data were anonymised using 1 and 2 codes for the appliance types during the analysis. Thus, the data analyst could not identify allocation group during data analysis. As soon as the allocation envelope was opened in preparation for appliance placement, both clinician and participant knew the type of appliance used. This allowed the clinicians to follow the recommended standard sequence of archwires for each appliance. Although patients were aware of the allocation group, they did not have previous experience with orthodontic treatment and could not recognise the difference between appliances.

Statistical analysis

The data were analysed using the Statistical Package for Social Sciences for Windows, version 22.0 (SPSS Inc., Chicago, Illinois, USA). The following statistical analyses were used:

Descriptive statistics: This included: number, mean, standard deviation, frequency, and percentages.

Reliability statistics: The intraclass correlation coefficient (ICC) was used to test intra-examiner reliability for 20 sets of study models (ABO CR-EVAL) and 25 cephalometric radiographs (incisor inclination) measured twice with a four weeks interval.

Inferential statistics: Levene's test was used to compare between-group variation. A "per-protocol" analysis was used. The two appliance groups were compared using: independent samples t-test and two-way ANOVA for continuous data, whilst a Chi-square, Mann-Whitney U test, and Wilcoxon signed-rank test were used for categorical data. The significance level was set as $p < 0.05$ except where a Bonferroni correction was applied to control type I error. A 95% confidence interval was estimated for the mean difference between the study groups.

RESULTS

Participant flow

One hundred and ninety-seven patients were enrolled in the study. Ten patients did not attend for appliance placement or declined to participate. Therefore, 187 patients were randomised to either the 0.018'' or 0.022'' group in a 1:1 ratio. The 34 (Figure 1) who were lost to follow-up or who either experienced a protocol deviation or where there was very poor compliance were excluded from the study. Therefore 153 patients were included in the analysis (overall mean age: 19.1 ± 8.5 years). Patient recruitment started in January 2010 and ended in September 2014 and the trial was completed as planned.

Baseline data

Baseline characteristics including; age at bonding, gender, type of malocclusion, pre-treatment PAR score, and the presence of extracted and impacted teeth were found to be similar in both treatment arms (Table 1). Moreover, assessment of the Pre-treatment Questionnaire can be considered as baseline data information to determine if any differences existed between patients in the two groups regarding their motivating influences and expectations toward orthodontic treatment. It did not show statistically

significant differences between the two treatment groups indicating that pre-treatment patient expectations were similar and this enhanced the homogeneity of groups (Table 2).

Numbers analysed for each outcome, estimation and precision, subgroup analyses

During the recruitment stage 216 patients were invited to participate in the study however, 19 patients declined and 197 participants were enrolled in the study (Figure 1). The number of analysed participants was 77 for the 0.018'' group and 76 for the 0.022'' group (total: 153 participants). The records analysed for each outcome were as follows: ABO CR-EVAL (145), PAR index (143), incisor inclination (128), patient expectations and experience (153), and patient satisfaction (142 patients). Although an intention-to treat analysis was carried out for the primary outcome, it was decided to use a "per-protocol" analysis for the secondary outcomes for two reasons: firstly, participants who were excluded were either not eligible to fulfill the protocol, failed to comply with treatment or moved to another hospital or practice. Most of the dropouts neither had completed treatment nor had reached a stage where outcomes could be predicted from the baseline data, so imputing their data would be a source of bias. Secondly, the analysed number of participants (145) for the leading secondary objective (ABO CR-EVAL) was found to be adequately powered (80.0%). The treatment outcome descriptions are presented in Table 3.

Reliability measurements

Calibration with the ABO CR-EVAL was considered sufficient after several repetitions of the measurement using the calibration kit until the results were comparable with the scoring sheet results provided by the ABO. The ICC revealed that intra-examiner agreements for the ABO CR-EVAL (0.95, N=20) and for both the U1-PP (0.97, N=25) and L1-MP (0.98, N=25) were excellent.

Outcome measurements

Comparison between the 0.018-inch and 0.022-inch slot bracket groups revealed statistically non-significant differences between the treatment arms for the ABO CR-EVAL, PAR index, incisor inclination, patient experience and satisfaction (Tables 3 to 7). There were statistically significant differences for the incisor inclinations between the pre-treatment and near end treatment stages (U1-PP, $p = 0.003$; L1-MP, $p = 0.007$) (Table 4). Similarly, a highly statistically significant improvement in aesthetics was noted between pre-treatment and post-treatment IOTN in both groups ($P < 0.01$) (Table 8).

The data were checked in respect of normality, homogeneity, and outliers. A Bonferroni correction was applied wherever there were multiple tests conducted on the same data and addressing the same hypothesis. Two extreme outliers were removed from the post-treatment PAR sample before analysis to minimise bias. A Mann-Whitney U test was used to assess the interproximal contact component of the CR-EVAL due to its heterogeneity.

Harms

No adverse events were reported during treatment.

DISCUSSION

The results of this RCT did not reveal significant differences between the 0.018-inch and 0.022-inch slot brackets in terms of quality of occlusal outcome and patient perception. Therefore, the null hypothesis was accepted.

Occlusal Outcomes/ABO CR-EVAL

The differences between the groups were minor with a mean total CR-EVAL score difference of 0.2. Neither the total CR-EVAL nor any of the constituent components showed statistically or clinically significant differences. The retrospective study by Detterline et al. (2010) (11) found that after adjusting for the covariates, only the alignment/rotation and the total scores were statistically significantly better for the 0.018-inch slot bracket group (26.3 ± 10.0) in comparison to the 0.022-inch slot bracket group (28.5 ± 11.3). The largest discrepancy for any component was 0.5 while in the present study this was 0.8

(marginal ridges). In both cases, these results did not show clinically relevant differences between the appliance groups. Regarding the total score difference, this was 2.7 points in the Detterline et al. study (11), while it was 0.22 in the present study. Unlike this study, the clinicians in the study by Detterline et al. (11) used a variety of bracket prescriptions and this variation in treatment philosophy could result in obfuscating the difference between the 0.018-inch and 0.022-inch slot bracket groups. This was avoided in the present study as variation in treatment between the groups was negligible because all the clinicians used identical brackets with MBT prescription and treatment strategies.

The mean total CR-EVAL score for the 0.018'' and 0.022'' groups were slightly above 34 points. These scores were considered high and above the acceptable limit (less than 30 points lost) to pass the ABO phase III board examination. The potential explanations for the high ABO CR-EVAL score in this study might be due to [1] the severity of pre-treatment malocclusion, [2] the type of malocclusion could also play a role in influencing ABO results. Significantly better ABO CR-EVAL scores have been found with Class I malocclusion when compared with Class II malocclusion. (27-28) In this study, Class II malocclusion accounted 52% and 44% in the 0.018'' and 0.022'' groups respectively and may explain the high ABO scores. [3] An association has been found between longer treatment duration and poorer ABO CR-EVAL scores, which has been mainly attributed or associated with decreased patient cooperation due to burn-out. (27,29-31) In the current study, although no significant association was found between treatment duration and poorer ABO scores [presented in Part 1(15)], it was noted that both the mean values for treatment duration and the ABO CR-EVAL scores were relatively high for both appliance groups. [4] The variation in the level of clinician experience (postgraduate students and orthodontic specialists) could account for adversely affecting the overall CR-EVAL scores in this study, and finally, [5] the current results represent a large pool of cases that have not been selected for quality assessment such as those usually presented for the ABO exam. The similarity in the baseline characteristics and treatment protocol revealed that differences in bracket slot size did not influence occlusal outcomes.

Both the sample size calculation for the total ABO CR-EVAL score and the intention-to-treat analysis for the primary outcome revealed the lack of impact of drop out patients.

Occlusal Outcomes/PAR index

This high percentage PAR score reduction in both groups could be explained by the high initial PAR score for both groups. Patients with high pre-treatment PAR scores have been found to demonstrate a greater reduction in the PAR score/improvement for their occlusion. (32-37) Furthermore, the initial similarity in pre-treatment malocclusion severity could explain the comparable degree of improvement between the two groups. As with the present study, Amditis and Smith (2000) (10) used the PAR scoring index to evaluate treatment outcome between the two bracket slot size systems. However, they did not provide any statistical comparison.

It can be assumed from the current RCT and from other RCTs that compared self-ligating and conventional brackets (38,39) that variation in bracket slot size or bracket design has little or no effect on quality of treatment outcome as measured with occlusal indices, whereas the effect of initial severity of malocclusion would be greater in determining the amount of orthodontic improvement.

Occlusal Outcomes/Incisor Inclination

In both 0.018'' and 0.022'' groups the U1-PP and L1-MP angles before and near end of treatment were consistent with the Eastman Standard for the UK Caucasian population (U1-PP = 109˚ ± 6˚ and L1-MP = 93˚ ± 6˚). (40) Both types of appliances had caused a statistically significant amount of incisor proclination near the end of treatment. The 0.018-inch slot bracket appliance proclined the maxillary and mandibular incisors by an average of 2.9˚ and 2.7˚, respectively. On the other hand, the 0.022-inch slot bracket appliance proclined the maxillary and mandibular incisors by an average of 1.6˚ and 1.4˚, respectively. Since these changes were small, they cannot be considered as clinically significant. Furthermore, the effect of bracket slot size was not statistically significant and both groups followed the same direction of change between the pre-treatment and near end of treatment stages i.e. there was no significant interaction between slot size and pre-treatment/near end of treatment.

The small difference in incisor inclination between the 0.018'' and 0.022'' groups could be related to the small amount of difference in the play between the working stainless steel wire and the 0.018-inch slot bracket (0.016 × 0.022-inch stainless steel, with an amount of play = 7.8˚) (41) and that with the 0.022-inch slot bracket (0.019 × 0.025-inch stainless steel, with an amount of play = 9.5˚) (41). Such a difference in play would be expected to be associated with a non-significant difference in the amount of incisor inclination between the two bracket slots.

By adding this RCT to the literature, it can be postulated that bracket type (design, prescription or slot size) alone seems to have a little effect on torque expression, (42-44) whereas the combination of slot size and archwires is responsible for the expression of torque.

Patient Perception

Comparison of Patient Expectation of Fixed Appliance Orthodontic Treatment

No significant differences were found between patients in the two treatment groups in their expectations of fixed appliance orthodontic treatment. The results revealed that patients are primarily concerned about anterior dental aesthetics and smiling and they might have thought that fixed appliances would have little effect on general facial aesthetics, occlusion of the posterior teeth and eating. It was also surprising to find that they did not consider their interaction with people as one of the major motivating factors for treatment. All these might reflect that they did not have problems with these aspects or they may have underestimated the effects of fixed appliance treatment and were particularly concerned about aesthetics more than functional or social aspects.

Comparison of Patient Experience with Fixed Appliance Orthodontic Treatment

Experience of Wearing a Brace

The patients in both treatment groups showed comparable experiences of wearing a brace. The similarity in the external design of both appliances used in this study may explain the non-significant difference between them especially for experiences such as ability to keep the appliances clean, while the nuisance reported by more than half of the participants was probably due to brackets physical interference with the cleaning process as well as the discomfort felt during cleaning.

Similarly, the overall experience of wearing appliances was not significantly different between the 0.018'' and 0.022'' groups. Nevertheless, the results slightly favoured the 0.018-inch slot brackets (positive experience: 57.7% and 48.3%, negative experience: 5.8% and 10.3%, respectively). The encouraging aspect is that in both appliance groups the negative feedback was in the minority, while the majority of patients found treatment worthwhile and would recommend it to others.

Self-Concept and Interpersonal Relations

The majority of patients reported either no change or an improvement in their appearance due to treatment and the results slightly favoured the 0.022'' group. Although this contradicts the former percentage of overall experience between groups, both were not statistically significant. Similarly, the effect of any change in appearance did not alter relationships with family and friends or alternatively showed an improvement only for a few participants. This may explain the low percentage of negative feedback for the overall experience with both groups.

Although patients who reported an improvement in appearance were 40.3% in the 0.018'' group and 47.4% in the 0.022'' group, a feeling of embarrassment was not reported by 83.1% in the 0.018'' group and 86.7% in the 0.022'' group. This may reflect the popularity of wearing fixed appliances and may indicate that patient self-esteem has improved six months after the start of treatment which was in accordance with de Couto Nascimento et al. (2016) (45), but disagreed with Prado et al. (2016) (46). In this study, the percentage of subjects who did not feel embarrassed due to wearing fixed appliances was 3.6% higher with the 0.022'' group and this reflected the slightly higher percentage of improvement in appearance in the 0.022'' group compared to the 0.018'' group.

Pain and Function

All the differences in terms of soreness in mouth and teeth were minor and did not reach the level of statistical significance between the two groups.

Eating followed a similar pattern in both groups. The difficulty with eating noted in the current study may be the result of pain reported by patients, following dietary instructions and the social embarrassment with eating, for instance, the longer time taken to eat and difficulty in cleaning the appliances. Part 3 of this study included the biological side effects and pain during treatment. (16)

Comparison of Patient Satisfaction with Fixed Appliance Orthodontic Treatment

Patients in both groups were satisfied with treatment outcomes with no significant differences being evident. However, the exception was that more patients in the 0.022'' group were dissatisfied about the occlusion of their posterior teeth. Although this may be coincidence spurious finding, it could be related to the difference in archwire sizes or the need for greater operator skill in finishing treatment using the 0.022 slot.

Both slot size groups showed a significant improvement in the self-perception of esthetics as assessed by the IOTN. This was consistent with the findings of the Post-treatment Questionnaire where patient satisfaction was noticeable in all dental and facial esthetic items. Therefore, both bracket slot sizes were effective in delivering satisfactory treatment results from the patient perspective. Concomitantly with the findings of the questionnaires, the IOTN scores revealed that no statistically significant differences were found between the 0.018'' and 0.022'' groups for both pre-treatment and post-treatment.

Limitations

Root angulation was not included in the ABO CR-EVAL due to the non-availability of a post-treatment dental panoramic radiograph (UK orthodontic radiography guidelines), however this was in line with different investigations have excluded the root angulation category. (31,47-51) The drawback of patient perception section of the study was that the validation process was carried out during the trial, therefore the newly added items related to tooth brushing (Pre- and Post-treatment Questionnaire) and smiling (Post-treatment Questionnaire) were not included in this analysis. Furthermore, not all records were available and although it was not possible for the data to be imputed, the study was adequately powered and as a result, data imputation may bias the results.

Generalisability

The external validity of the study was high as all eligible participants were recruited from a complete cohort presenting for state-funded orthodontic treatment in hospitals in the same health board area. However, the current study was undertaken in a teaching hospital environment which might be different from orthodontic practice in primary care as the cohort included patients with all malocclusion types and both extraction and non-extraction cases.

This study overcame some drawbacks associated with previous investigations. This was accomplished by longitudinally investigating patient perception throughout fixed appliance orthodontic treatment in an RCT using validated questionnaires for different age groups and focusing on the patient perspective of treatment as opposed to parental views.

Opportunities for Future Clinical Research

The suggestion of Rubin (2001) (1), Peck (2001) (2) and Kusy (2002) (4) to adopt one slot size in order to standardise pre-adjusted fixed appliance orthodontic treatment biomechanics can be supported. This could be either of these slots (or a hybrid appliance of both) or a new slot size, for example, 0.020-inch slot bracket. The standardised slot size could be developed and then tested for both labial and lingual appliances incorporating the technological advances that have been made with customised labial appliances.

CONCLUSIONS

There is insufficient evidence to determine statistically or clinically significant differences in the quality of occlusal outcomes, incisor inclination and patient perception of orthodontic treatment between the 0.018-inch and 0.022-inch slot conventional ligation MBT bracket systems. Both bracket slot sizes can provide an equally effective quality of treatment.

Dental aesthetics was the main factor associated with expectation and satisfaction with orthodontic treatment. During treatment, some pain and functional limitations were detected but they were also associated with positive features such as improvement in appearance with no negative impact on social life.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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